K011218

MAY 1 6 2001

Exactech® AcuMatch™ Integrated Hip System
L-Series Size 1 Cemented Femoral Stem

510(k) Summary of Safety and Effectiveness

Trade Name: Exactech® AcuMatch L-Series
Cemented Femoral Stem Component (Size 1)

Common Name: Femoral Stem

Classification Name: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented, (Femoral Component)

Legally Marketed Devices for Substantial Equivalence Comparison:

Model	Manufacturer
L-Series (Sizes 2-5)	Exactech (#K001335)
AuRA	Exactech (#K961304)
Conquest FX	Smith & Nephew
Spectron	Smith & Nephew
PFC	Depuy

Substantial Equivalence Information:

The Exactech size 1 AcuMatch L-Series Cemented Femoral component has similar indications and contraindications as other femoral components legally marketed in the United States. The size 1 L-Series device has similar technological features to other devices, most notably Exactech's predicate L-Series design (sizes 2-5) cleared through premarket notification #K001335 and Exactech's AuRA cemented stem cleared through premarket notification #K961304. In addition, the proposed L-Series size 1 component is similar to femoral components legally marketed by other manufacturers. These include the "Conquest FX" and "Spectron" by Smith & Nephew and the "PFC" by Depuy. The Conquest FX model like the L-Series is manufactured from cast cobalt chrome. Other similarities between the predicate stems and the proposed L-Series design include a satin surface treatment and a proximal to distal taper. All of the components are supplied sterile. Three-Point fatigue testing of the Exactech L-Series device places the strength of the stem in the range of other legally marketed devices.

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Indications for Use:

AcuMatch L-Series Cemented Femoral Stem Components are indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, congenital hip dysplasia, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for revision of failed previous reconstructions where sufficient bone stock is present and to restore mobility resulting from previous fusion.

AcuMatch L-Series Cemented Femoral Stem Components are intended to be used with bone cement.

Contraindications:

AcuMatch L-Series Cemented Femoral Stem Components are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system.

Device Description:

L-Series Femoral Stem Components are made from cast Cobalt Chromium Molybdenum alloy conforming to ASTM F 75-98. Mechanical properties for ultimate strength, ductility, and grain structure are controlled by this specification. The L-Series components have a satin finish and are intended for cemented applications only.

Packaging, Labeling and Sterilization:

L-Series components are first packaged at Exactech in a certified Class 100,000 Cleanroom. The products are then shipped to an ISO/EN certified Irradiation Facility and returned to Exactech where they are quarantined pending a final product inspection. Qualifying implants are then released for distribution. Packaging materials are outlined in the following table.

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Material	Composition
Inner / Outer Trays	PETG – 0.040" thickness
Tray Lids	Spun-Bonded Olefin - Tyvek®
Inserts	Medium grade LD45 Foam
Box	Heavy weight cardboard
Outer Shrink-Wrap	Clear, Light-Weight Plastic
Shipping Cartons	Heavy-weight Corrugated Cardboard

Utilization and implantation instructions are included in the package insert provided with each product. The name, size, dimension, material, lot, serial number and sterility status are indicated on the labeling.

Sterilization Specifications:

Method: Gamma radiation (Cobalt 60 source)
Dose: 25 – 37 kGy
Sterility Assurance Level (SAL): 10^{-6}

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2001

Ms. Lisa Simpson
Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K011218
Trade Name: Exactech® AcutMatch Integrated Hip System L-Series Size 1 Femoral Stem Component
Regulation Number: 888.3350
Regulatory Class: II
Product Code: JDI
Dated: April 18, 2001
Received: April 20, 2001

Dear Ms. Simpson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® AcuMatch™ Integrated Hip System
L-Series Size 1 Cemented Femoral Stem

Indications for Use

510(k) Number: K011218

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L-Series Cemented Femoral Stem Component (Size 1)

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(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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510(k) Number K011218

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over the Counter Use _____